REMARKS

This paper is filed in response to the Office Action mailed April 2, 2010. Claims 1-9, 20-26, 34-38, and 75-89 were before the Examiner for consideration. In this paper, Claims 36, 79, 83, and 86 have been amended, Claims 78 and 82 have been canceled, and no new claims have been added. Accordingly, Claims 1-9, 20-26, 34-38, 75-77, 79-81, and 83-89 are now before the Examiner for consideration. No new matter has been added in these amendments.

Summary of the Office Action

In the Office Action, the specification was objected to on the basis of certain informalities. Claims 36, 79, and 82 were objected to on the basis of certain informalities. Claims 83 and 86 were rejected under 35 U.S.C. §112 as failing to comply with the written description requirement. Claim 87 was rejected under 35 U.S.C. § 112 as being indefinite. Claims 84 and 88 were rejected under 35 U.S.C. § 102(b) as being anticipated by Lafontaine (US Patent No.6,520,939). Claims 85-87 and 89 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Lafontaine in view of Haberland et al. (US Patent Application Publication No.2005/0165433). Claims 1, 3-9, 20-24, 34, 75, and 76 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Lafontaine in view of Haberland. Claim 2 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Lafontaine and Haberland further in view of Fischell et al. (U.S. Patent No. 6,017,328). Claims 25-26 were rejected under 35

U.S.C. § 103(a) as being unpatentable over Lafontaine in view of Haberland further in view of Green et al. (US Patent No.6,497,716). Claims 35-38 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Lafontaine in view of Haberland further in view of Willis et al. (U.S. Patent No. 6,767,340). Claims and 77, 79, 80, and 81 were rejected under 35 U.S.C. §103 (a) as being unpatentable over Lafontaine in view of Willis. Claims 78 and 82 were rejected under 35 U.S.C. §103 (a) as being unpatentable over Lafontaine in view of Willis in view of Hart. Claim 83 was rejected under 35 U.S.C. §103 (a) as being unpatentable over Lafontaine in view of Willis and further in view of Haberland. For at least the reasons discussed below, Applicant respectfully traverses these rejections.

Regarding the Objections to the Specification

As noted above, the specification was rejected to on the basis of certain informalities. More specifically, the abstract of the disclosure was objected to because of its length, and the use of the trademark Kraton in the specification had been noted and its capitalization requested. In the above section entitled "Amendments to the Specification," Applicant has directed the entry certain amendments which address these informalities. Accordingly, the objections to the specification are not applicable, and Applicant respectfully requests the withdrawal of same.

Regarding the Objections to the Claims

As noted above, Claims 36, 79, and 82 were objected to on the basis of certain informalities. More specifically, a trademark was noted in Claims 36 and 79, a misspelling was noted in Claim 79, and a missing word was noted in Claim 82. In the above section entitled "Amendments to the Claims," Applicant has amended to address these informalities. Accordingly, the objections to the claims are no longer applicable, and Applicant respectfully requests the withdrawal of same.

Regarding the Rejections under 35 U.S.C. §112

As noted above, Claims 83 and 86 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. While the specification as-filed, including the written description and drawings, does provide support for the bonding feature as previously-recited, Applicant has amended Claims 83 and 86 to more closely track the language of the written description.

Once again, Applicant notes that it is well established that there is no requirement for an in haec verba, that is, word-for-word, correspondence between the specification as filed and the claim terminology (see, e.g., M.P.E.P. 2163.02, stating that the "subject matter of the claim need not be described literally (i.e., using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement."). Accordingly, the above amendments are made merely to expedite prosecution of the pending claims and no acquiescence or estoppel should be implied

thereby.

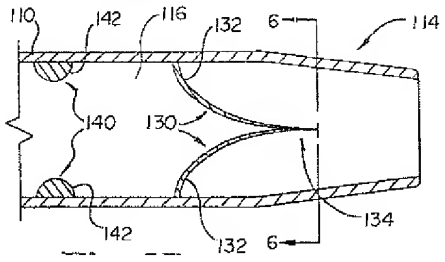
As noted above, Claim 87 was rejected under 35 U.S.C. §112 second paragraph as being indefinite. In this paper, Applicant has amended Claim 87 to recite that "the zero seal is coupled to the septum seal by fusing." Accordingly, this rejection is not applicable to Claim 87, and Applicant respectfully requests the withdrawal thereof.

The Recited Subject Matter Is Distinguishable over Lafontaine.

As noted above, in the Office Action, Claims 84 and 88 were rejected as being anticipated by Lafontaine. For at least the reasons discussed below, Applicant respectfully traverses these rejections.

Lafontaine relates to a hemostasis valve for use with vascular introducer sheaths, catheters, Y-adapters, and the like. (Lafontaine, col. 1, lines 6-9). As illustrated in Figure 5A, reproduced below, Lafontaine describes an introducer sheath including an active hemostasis valve 130 and a passive hemostasis valve 140. (Lafontaine, col. 4, lines 6-7). The active hemostasis valve 130 comprises a plurality of leaflets or flaps 132. (Lafontaine, col. 4, lines 30-31). The passive hemostasis valve 140 is normally open to allow devices to freely pass therethrough, and comprises a flexible polymeric O-ring sized to create either an interference fit or a gap fit with a device inserted therethrough. (Lafontaine, col. 4, lines 47-64).

Fig. 5A



Lafontaine teaches away from using a "gasket" seal comprising a disk with the device disclosed therein. In connection with the background to the Lafontaine device, Lafontaine does describe a "gasket" comprising a "disc of flexible polymeric material having" a hole or slit therethrough. (See, e.g., Lafontaine, col. 1, lines 27- 41, Figures 2A, 2B). However, Lafontaine describes these gasket configurations only in relation to admitted prior art vascular access systems that, unlike the access device recited in Claim 1, do not include another seal. Furthermore, Lafontaine emphasizes perceived undesirable performance characteristics of each of these gasket configurations to assert the desirability of the O-ring. (Lafontaine, col. 1, lines 42-55). Thus, Lafontaine teaches away from using one of the described gaskets as either an active hemostasis valve or a passive hemostasis valve in the described surgical access device.

In contrast to the Lafontaine device, Claim 84 relates to a surgical access device comprising, among other limitations, an elongate tubular and a seal system at the distal end of the tubular member. The seal system comprises, among other limitations, "a septum seal comprising a septum having an orifice sized and configured to seal in conjunction with a specific range of usable instruments" and "a zero seal

coupled to the septum seal and being sized and configured to seal when no instrument is in place within the working channel of the tubular member." Claim 88 depends from Claim 84 and further recites that "the septum seal and the zero seal are formed in a monolithic construction."

As discussed above, Lafontaine fails to disclose a septum seal comprising a septum and an orifice as recited in Claim 84. Rather, Lafontaine describes an O-ring positioned in an elongate shaft to provide sealing under certain conditions. Applicant notes that during examination, the claim terms are entitled to their broadest reasonable interpretation, consistent with the interpretation that one of skill in the art would reach. (See, e.g., M.P.E.P. 2111). Applicant respectfully submits that there is no *reasonable* interpretation of a septum seal comprising a septum that would include the O-ring of the Lafontaine device.

Lafontaine likewise fails to disclose a septum seal and zero seal "formed in a monolithic construction," as recited in Claim 88. As previously discussed Lafontaine illustrates the O-ring with hatching to indicate it is a "juxtaposed different element" with respect to the sheath, even though the valve of Figure 5A is expressly indicated to be an "integral part" of the sheath. (Lafontaine, col. 4, lines 18-22; 37 C.F.R. § 1.84(h)(3)). Thus, Lafontaine has disclosed an O-ring that has been separately formed and later integrated with the sheath, but not the recited "integrally formed" device. Accordingly, Applicant respectfully submits that there is no *reasonable* interpretation of "formed in a monolithic construction," that would include components separately formed and later

assembled, as if asserted in the Office Action.

Accordingly, for at least the reasons discussed above, Lafontaine fails to disclose all of the recitations of Claims 84 and 88. Thus, Claims 84 and 88 are distinguishable over the applied art.

The Recited Subject Matter Is Distinguishable over Combinations the Lafontaine with Other References.

As noted above, Claims 85-87 and 89 were rejected as being unpatentable over Lafontaine interview of Haberland. Claims 85-87 and 89 depend from Claim 84 and recite additional novel and non-obvious limitations thereon. As discussed above, Lafontaine fails to disclose all of the recitations Claim 84. Haberland likewise fails to disclose the deficiencies of the Lafontaine with respect to Claim 84. For example, as noted above, Lafontaine fails to disclose a surgical access device comprising a seal system at the distal end of an elongate tubular member having "a septum seal comprising a septum." Haberland likewise fails to disclose a seal system at the distal end of an elongate tubular member having a septum seal. Rather, Haberland relates to a trocar system including a valve housing detachably connected to a proximal portion of a cannula body and at least one septum valve positioned in the valve housing. Haberland, paragraph [0013]). Accordingly, while Haberland does describe a construction process for a proximally-positioned cap assembly 30 in paragraphs [0048]

and [0049], Haberland fails to disclose or suggest such a process for a seal system "at the distal end" of a tubular member, as recited in Claim 84.

Accordingly, for at least the above reasons, Claim 84 is distinguishable over the combination of Lafontaine and Haberland. Thus, Claims 85-87 and 89, which depend from Claim 84 are likewise distinguishable over the applied combination of references.

As noted above, Claims 1, 3-9, 20-24, 34, 75, and 76 were rejected as being unpatentable over the combination of Lafontaine with Haberland. For at least the reasons discussed below, Applicant respectfully traverses these rejections.

Claim 1 relates to a surgical access device comprising, among other recitations, an elongate tubular member, a septum seal integrally formed at the distal end of the tubular member, and a zero seal disposed at the distal end of the tubular member and distal to the septum seal. The septum seal comprises, among other limitations, "an elastomeric sheet having a frusto-conical shape and an orifice through the elastomeric sheet."

As discussed above, Lafontaine fails to disclose or suggest a septum seal as recited in Claim 1, given its broadest reasonable interpretation consistent with the interpretation one skilled in the art would reach. Rather, Lafontaine describes an O-ring positioned in an elongate shaft to provide sealing under certain conditions. While Lafontaine does indicate that the O-ring can be "an integral part" of the device as

opposed to a releasably connected assembly, Lafontaine fails to disclose or suggest that the O-ring is integrally formed with the tubular structure. (Lafontaine, col. 4, lines 13-22). Instead, Lafontaine illustrates the O-ring with hatching to indicate it is a "juxtaposed different element" with respect to the sheath, even though the valve of Figure 5A is expressly indicated to be an "integral part" of the sheath. (Lafontaine, col. 4, lines 18-22; 37 C.F.R. § 1.84(h)(3)). Thus, Lafontaine has disclosed an O-ring that has been separately formed and later integrated with the sheath, but not the recited "integrally formed" device.

Haberland fails to remedy to the deficiencies of Lafontaine with respect to Claim 1. For example, Haberland fails to disclose a septum seal that has a frusto-conical shape or that is "integrally formed" at the distal end of a tubular member. Haberland relates to a device having a "planar" septum seal having a "relatively flat thin profile". (Haberland, title, paragraph [0055]). Haberland illustrates a septum valve having a planar valve body 55 with a valve opening 51 "adapted to individually and separately receive a plurality of different elongate tools," to maintain a septum seal between peripheries of the valve body 55 surrounding the valve opening 51 and abuttingly contacting outer peripheries of one of the tools extending therethrough (Haberland, paragraph [0043], Figure 15c). The septum valve includes a periphery valve section 57 with convolutes 58 and rib portions 59 about the periphery thereof. (Haberland, paragraph [0044]). The periphery valve section 57 does not form a septum seal with tools inserted therethrough. Accordingly, Haberland fails to disclose a septum seal

having a frusto-conical shape, as recited in Claim 1.

Furthermore, Haberland fails to disclose or suggest a septum seal that is "integrally formed" at the distal end of the tubular member, as recited in Claim 1. Rather, as discussed above, in the Haberland device, a septum valve is positioned within a valve housing at the proximal end of a cannula. Thus, the Haberland valve members are not "integrally formed," nor positioned at the distal end of the tubular member, as recited in Claim 1.

-- One Skilled in the Art Would Be Dissuaded by Lafontaine from Incorporating a Valve Member from the Haberland Device Therein.

As discussed above, Lafontaine fails to disclose all of the elements of the recited surgical access device. For example, Lafontaine fails to disclose a septum seal comprising an elastomeric sheet having a frusto-conical shape and an orifice through the elastomeric sheet, as is recited in Claim 1. Furthermore, one skilled in the art would be dissuaded by Lafontaine from modifying the device therein to include a valve member as described in Haberland. Rather, as discussed above, Lafontaine teaches away from the use of a disk-shaped "gasket" similar to the valve members of Haberland, repeatedly emphasizing the perceived disadvantages of these valve members.

Accordingly, for at least the reasons discussed above, Claim 1 is distinguishable over the applied art. Claims 3-9, 20-24, 34, and 75-76 depend from Claim 1 and recite

additional novel and nonobvious limitations thereon. Therefore, Claims 3-9, 20-24, 34, and 75-76 are distinguishable over the applied art for at least the reasons discussed above with respect Claim 1.

The Recited Subject Matter Is Distinguishable over the Applied Combination of Lafontaine, Haberland, and Fischell.

As noted above, Claim 2 was rejected as being unpatentable over Lafontaine and Haberland further in view of Fischell. For at least the reasons discussed below, Applicant respectfully traverses this rejection.

Claim 2 depends from Claim 1 and recites additional novel and nonobvious limitations thereon. For at least the reasons discussed above, Claim 1 is distinguishable over the applied combination of Lafontaine and Haberland. Fischell likewise fails to disclose or suggest the deficiencies of Lafontaine and Haberland with respect to Claim 1. For example, Fischell fails to disclose or suggest a device having a septum seal having a frusto-conical shape that is "integrally formed" at the distal end of a tubular member. Rather, Fischell relates to injection ports for sub-cutaneous delivery of medication that includes a one-piece main body 11 and a separate self-sealing, soft, disk-shaped elastomer septum 22 positioned within the main body 11. (Fischell, col. 1, lines 10-11, col. 5, lines 36-39, col. 6, lines 4-8).

Accordingly, for that least the reasons above, the applied combination of references fails to disclose or suggest all of the recitations of Claim 1, from which Claim

2 depends. Thus, Claim 2 is distinguishable over the applied combination of references.

The Recited Subject Matter Is Distinguishable over the Applied Combination of Lafontaine, Haberland, and Green.

As noted above, Claims 25 and 26 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Lafontaine and Haberland in view of Green et al. Claims 25 and 26 depend from Claim 1 and recite additional novel and nonobvious limitations thereon. As discussed above, the applied combination of Lafontaine and Haberland fails to disclose or suggest all of the limitations of Claim 1. Green appears to have been relied on in the Office Action solely for its asserted disclosure of a specific shape of certain portions of a placement device. Green thus fails to disclose or suggest the deficiencies of Lafontaine and Haberland with respect to Claim 1.

Accordingly, for at least the reasons discussed above, the applied combination of references fails to disclose or suggest all of the limitations of Claim 1, from which Claims 25 and 26 depend. Therefore, at least for the reasons that Claim 1 is distinguishable over the applied combination of references, Claims 25 and 26 are distinguishable over the applied combination of references.

The Recited Subject Matter Is Distinguishable over the Applied Combination of Lafontaine, Haberland, and Willis.

As noted above, Claims 35-38 were rejected as being unpatentable over Lafontaine in view of Haberland further in view of Willis. Claims 35-38 depend from Claim 1 and recite additional novel and nonobvious limitations thereon. As discussed above, the applied combination of Lafontaine and Haberland fails to disclose or suggest all of the limitations of Claim 1. Willis appears to have been relied on in the Office Action solely for its asserted disclosure of certain aspects of a duckbill seal. Willis thus fails to disclose or suggest the deficiencies of Lafontaine and Haberland with respect to Claim 1.

Accordingly, for at least the reasons discussed above, the applied combination of references fails to disclose or suggest all of the limitations of Claim 1, from which Claims 35-38 depend. Therefore, at least for the reasons that Claim 1 is distinguishable over the applied combination of references, Claims 35-38 are distinguishable over the applied combination of references.

The Recited Subject Matter Is Distinguishable over the Applied Combination of Lafontaine and Willis.

As noted above, Claims 77, 79, 80, 81 were rejected as being unpatentable over Lafontaine in view of Willis. Claimed 77 relates to a surgical access device, comprising, among other limitations, an elongate tubular member, a septum seal

integrally formed at the distal end of the tubular member, the septum seal comprising an elastomeric sheet and an orifice through the elastomeric sheet, and a duckbill valve positioned distal of the septum seal. For at least the reasons discussed above with respect to Claims 1 and 84, Lafontaine fails to disclose suggest the recited septum seal. Willis likewise fails to disclose or suggest a septum seal as recited. Willis describes that a duckbill valve is formed from flange portion 68 and walls 70 and 72. (Willis, col. 3, line 60-col. 4, line 1). Moreover, in Figure 4, asserted in the Office Action to show an orifice through a septum, Willis illustrates an external side view of a valve member. Figure 3, which illustrates a cross-sectional view of the Willis device, plainly shows no septum seal, as recited in Claim 77.

Accordingly, for at least the reasons discussed above, the applied combination of references fails to disclose or suggest all of the limitations of Claim 77. Claims 79, 80, and 81 depend from Claim 77 and recite additional novel and non-obvious limitations thereon. Therefore, at least for the reasons that Claim 77 is distinguishable over the applied combination of references, Claims 79, 80, 81 are distinguishable over the applied combination of references.

Regarding Claims 78 and 82.

As noted above, Claim 78 and 82 were rejected as being unpatentable over Lafontaine in view of Willis further in view of Hart. In this paper, Claim 78 and 82 have been canceled without prejudice. Accordingly, these claim rejections are not applicable

to the pending claims, and Applicant respectfully requests withdrawal thereof.

The Recited Subject Matter Is Distinguishable over the Applied Combination of Lafontaine, Willis, and Haberland.

As noted above, Claim 83 was rejected as being unpatentable over Lafontaine in view of Willis further in view of Haberland. Claim 83 depends from Claim 77 and recites novel and nonobvious limitations thereon. For at least the reasons discussed above, Claim 77 is distinguishable over the combination of Lafontaine and Willis. Haberland fails to remedy the deficiencies of Lafontaine and Willis with respect to Claim 77. For example, as discussed in greater detail above, none of Lafontaine, Willis, and Haberland, alone or in combination, disclose or suggest "a septum seal integrally formed at the distal end of the tubular member, the septum seal comprising an elastomeric sheet and an orifice through the elastomeric sheet."

Accordingly, for at least the reasons discussed above, Claim 77 is distinguishable over the combination of Lafontaine, Willis, and Haberland. Thus, Claim 83, which depends from Claim 77 is distinguishable over the applied combination of references for at least the reasons discussed above with respect to Claim 77.

Conclusion

For at least the foregoing reasons, it is respectfully submitted that the rejections set forth in the outstanding Office Action are inapplicable to the present claims.

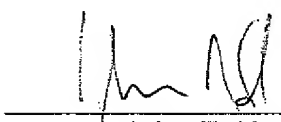
Accordingly, issuance of a Notice of Allowability is most earnestly solicited.

Applicant respectfully traverses each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches. Although amendments have been made, no acquiescence or estoppel is or should be implied thereby. Any arguments in support of patentability and based on a portion of a claim should not be taken as founding patentability solely on the portion in question; rather, it is the combination of features or acts recited in a claim which distinguishes it over the prior art.

The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call Applicant's attorney, John F. Heal, at (949) 713-8283 to resolve such issues promptly.

Respectfully Submitted,

APPLIED MEDICAL RESOURCES

BY 

John F. Heal
Reg. No. 53,008
(949) 713-8283